

METHOD AND SYSTEM FOR ASSISTING APPLICATION PREPARATION

## BACKGROUND OF THE INVENTION

5           The present invention relates to a method and system for assisting application preparation, and more particularly, to a method and system for assisting application preparation for assisting the preparation of application documents for making a document-based  
10 application to a public organization.

          A technique described, for example, in JP-11-328288 or the like is known as a prior art technique related to the assistance for application preparation. This prior art relates to a system for collectively  
15 managing a variety of slips, even if the slips for application procedures require different formats, to permit efficient procedures for a variety of applications. Specifically, the system searches a database which stores data related to a variety of  
20 slips for a slip for use in a required application procedure in response to a request from a user, and assists the user in operations involved in filling required items in associated fields on the slip, and submitting the completed slip.

25           Another known prior art technique permits the user to manually specify pertinent document data for association such that the user prepares an application which complies with a predefined application format in

the United States of America or some of European countries.

In recent years, activities have been promoted in the pharmaceutical industry and the like, 5 for defining a variety of application documents related to drugs as a world-wide standard, and separately providing local criteria in each country. Also, the acceptance of a variety of documents through electronic applications in the government and public organizations 10 tends to spread not only in the pharmaceutical industry but also in other business fields. Further, due to re-organization of enterprises within an industry, it is not unusual that an enterprise belonging to a certain country makes the same application in other countries. 15 Then, like the drugs, it is often the case that a drug which has previously accepted a permission in an advanced country is often applied again in other countries.

## 20 SUMMARY OF THE INVENTION

While the foregoing prior art techniques can alleviate to some degree the effort of the operator in preparing an application under the situation as mentioned above, they have the following problems. The 25 prior art techniques are incapable of alleviating the effort of preparing applications in different formats, even with the same contents, from one country to another or from one public organization to another.

Also, since they encounter difficulties in reusing data on previously permitted applications, the operator must newly prepare an application again each time an application is made.

5           It is an object of the present invention to provide a method and system for assisting application preparation which solves the aforementioned problems inherent in the prior art techniques, and is capable of capturing information on standards of applications,  
10 examination criteria and the like, determined by each country and each organization, to assist in preparing applications which comply with such standards.

          It is another object of the present invention to provide a method and system for assisting  
15 application preparation which is capable of referencing information on application documents which have already been applied to or permitted by a certain country or organization to reuse data included in the documents and assisting in conveniently preparing an application  
20 for another country or organization.

          It is a further object of the present invention to provide a method and system for assisting application preparation which is capable of storing a log of operation procedures created by the application  
25 preparation assisting system of the present invention to readily provide viewable information as audit data at some later time.

          According to the present invention, the

foregoing objects are achieved in an application preparation assisting method for assisting in preparing an application for making a document-based application to a public organization by acquiring information on a world-wide standard which defines contents that should be described in the application, acquiring information on a standard unique to each country which is defined in detail in conformity to the world-wide standard, and information on published application and examination unique to each country, and assisting in preparing application documents based on the acquired information on the world-wide standard, information on the standard unique to each country, and information on the application and examination.

Also, the foregoing objects are achieved in an application preparation assisting system for assisting in preparing an application for making a document-based application to a public organization, by comprising means for acquiring and utilizing information on a world-wide standard which defines contents that should be described in the application, means for acquiring and utilizing information on a standard unique to each country which is defined in detail in conformity to the world-wide standard, and information on published application and examination unique to each country, and means for assisting in preparing application documents based on the acquired information on the world-wide standard, information on

the standard unique to each country, and information on the application and examination.

#### BRIEF DESCRIPTION OF THE DRAWINGS

5           Fig. 1 is a diagram for explaining an outline of general activities for use with a system for assisting application preparation according to one embodiment of the present invention;

10           Fig. 2 is a block diagram illustrating the configuration of the system for assisting application preparation according to one embodiment of the present invention;

            Fig. 3 is a diagram showing an example 301 of a reference document specifying screen;

15           Fig. 4 is a diagram showing an example of a screen for converting a reference document to a document for a country to which an application is made;

            Fig. 5 is a flow chart for explaining the processing operation for converting a reference  
20 document to a document for a country to which an application is made;

            Fig. 6 is a diagram showing an example of a screen for automatically converting a reference document to an application defined by a country B;

25           Fig. 7 is a diagram showing an example of an application processing confirmation screen;

            Fig. 8 is a flow chart for explaining the processing operation for an examination content

confirmation unit to confirm whether or not any description violates examination criteria in the country B;

Fig. 9 is a diagram showing an example of a data matching screen for changing contents described in an application;

Fig. 10 is a flow chart for explaining the processing operation in a document data matching unit; and

Fig. 11 is a diagram showing an example of an application submission screen.

#### DESCRIPTION OF THE EMBODIMENTS

In the following, an embodiment of a method and system for assisting application preparation according to the present invention will be described in detail with reference to the drawings.

Fig. 1 is a diagram for explaining an outline of general activities for use with the system for assisting application preparation according to one embodiment of the present invention. In Fig. 1, the illustrated general configuration comprises a world-wide standard information database 102; published information databases 103, 105; application document information 104, 107; and an application preparation assisting system 106. The example illustrated in Fig. 1 may be applied to the preparation of application documents for a plurality of countries or public

organizations, wherein referring to contents of documents applied to an organization in one country, an organization in a country A, in the illustrated example, the system assists in preparing documents  
5 applied to an organization in another country, a country B in the illustrated example. Also, while the example illustrated in Fig. 1 assumes that the countries A, B are separate independent countries, they may be different public organizations in the same  
10 country.

In Fig. 1, the world-wide standard information database 102 is a database which accumulates information related to globally world-wide standards managed by a public organization in a third  
15 country or the like, including the countries A, B (also including public organizations in the respective countries). While the application preparation assisting system 106 is shown to be installed in the country B, it may be installed in the country A or any  
20 other country. Then, the database 102 which accumulates information related to the globally world-wide standards managed by the public organization in the third country or the like, and the application preparation assisting systems 106 installed in a  
25 plurality of countries are interconnected through a network such as the Internet, a public communication path or the like.

In an environment in which the application



preparation assisting system is used as illustrated in Fig. 1 described above, assume now that application documents are prepared with reference to world-wide standard information within the world-wide standard information database 102 and published information within the published information database 103 defined in the country A, and are accumulated as application document information 104. The published information 103 defined in the country A may be information on standards, formats of applications, mode, language, application procedure, examination criteria and the like which are uniquely determined by the country A, in addition to the world-wide standard. The prepared application documents may be prepared under the assistance of an application preparation assisting system, not shown in Fig. 1, which is installed in the country A, or may be prepared under the assistance of the shown application preparation assisting system 106 installed in the country B which may be accessed through the network. In preparing the application documents, the application preparation assisting system acquires published information within the published information database 103 through the network, preserves the acquired information as internal data, and updates the preserved information for utilization at a predefined timing. Here, the prepared application document information 104 may be documents under preparation by the application preparation assisting

system, or may be information which has already been applied and accepted, or information which has been permitted as a result of an examination after the application. The permitted information may be  
5 published as the published information 103 in some cases.

Next, description will be made on the preparation of application documents for the country B by referring to the application document information  
10 104 prepared in the country A, and reusing data in the referenced information. As is the case with the country A, in the country B, application documents 107 for the country B are prepared with reference to the published information 105 in the country B. In this  
15 event, the application preparation assisting system 106 references the application document information 104 in the country A to prepare the application documents 107 using a method of reusing data in the information, instead of a method of newly preparing the application  
20 documents. The application documents 107 thus prepared by utilizing the application preparation assisting system 106 in the country B are submitted electronically or in a document form to a public organization of interest in the country B.

25 Fig. 2 is a block diagram illustrating the configuration of the application preparation assisting system 106. In the following, the configuration of the system will be described. In Fig. 2, the system 106

comprises a world-wide standard reference unit 201; a world-wide standard information internal data creation/storage unit 202; country-based published information reference units 203, 205; country-based published information internal data creation/storage units 204, 206; a country-based internal data cross reference unit 207; a document preparation management assisting unit 208; a reference document specifying unit 209; an application document specifying unit 210; a pertinent document data detection unit 211; an automatic document conversion unit 212; an automatic translation unit 213; a format conversion unit 214; an examination content confirmation unit 215; a document data matching unit 216; a document data correlation rule defining unit 217; an application processing unit 218; and an manipulation log preservation unit 219.

The application preparation assisting system 106 is comprised of the components as illustrated in Fig. 2, and each of the components is configured to permit mutual communications of information as required. First, each of the components will be generally described.

The world-wide standard reference unit 201 is provided for referencing the globally world-wide standard information, and information acquired by the reference unit 201 is recast as internal data and stored in the world-wide standard information internal data creation/storage unit 202. The country-A

published information reference unit 203 references  
published information in the country A, and information  
acquired by the reference unit 203 is recast as  
internal data and stored in the country-A published  
5 information internal data creation/storage unit 204.  
Likewise, the country-B published information reference  
unit 205 references published information in the  
country B, and information acquired by the reference  
unit 205 is recast as internal data and stored in the  
10 country-B published information internal data  
creation/storage unit 206. The country-A internal  
data/country-B internal data cross reference unit 207  
compares application document information in the  
country A with application document information in the  
15 country B.

The document preparation management assisting  
unit 208, which assists for preparing application  
documents, can use an existing document management  
system. The reference document specifying unit 209  
20 specifies application document information to be  
referenced (in the example herein described, the  
application document information in the country A).  
The application document specifying unit 210 specifies  
specifying conditions associated with application  
25 documents to be prepared. The pertinent document data  
detection unit 211 confirms the existence of data which  
can be reused under conditions specified by the  
reference document specifying unit 209 and application

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document specifying unit 210, and provides such data, if any, to the user.

The automatic document conversion unit 212 applies conversion processing for the country B to reusable data detected by the pertinent document data detection unit 211. For this purpose, the automatic document conversion unit 212 is comprised, for example, of the automatic translation unit 213 for translating the language, the format conversion unit 214 for converting a format, and the like.

The examination content confirmation unit 215 is a functional unit for previously checking whether or not prepared documents include items which violate the examination criteria. Assume herein that the prepared documents include a description which does not comply with the examination criteria defined in the country B. In this event, the document data matching unit 216 replaces pertinent data for the portion of description which does not comply with the examination criteria to match the documents to the examination criteria. In this event, the document data matching unit 216 utilizes information on a correlation between respective data for matching, which is previously defined in the document data correlation rule defining unit 217.

The application processing unit 218 executes electronic application processing for the application documents after the examination content confirmation

unit 215 confirms that the application documents do not violate the examination criteria. The application documents may be preserved for utilization in an application at a later time, or may be printed for  
5 submission.

The manipulation log preservation unit 219 can preserve an entire log of manipulations performed on the system for preparing the application documents as mentioned above for viewing as information for audit  
10 or the like at a later time.

Next, the activities of the foregoing main components will be described with reference to examples of displayed screens and manipulation procedures on the screens.

15 Fig. 3 is a diagram showing an example 301 of a reference document specifying screen. In this example, assume for purposes of explanation that reference is made to application documents for the country A which have previously applied and permitted.  
20 First, a permitting country is selected with a selection button 302, and a keyword is entered in an article name entry field 303 or a search keyword entry field 304 for searching documents. Assume in this  
25 example that the article name is known, and the article name "gastrointestinal drug Alpha" has been entered in the entry field 303. As a result of search (in the figure, the progress of the search is indicated by the arrow), a search result 306, which can be referenced,

is displayed in a document 305 found by the search.  
Since "Document No. XXX on Gastrointestinal Drug Alpha  
Permitted in Country A" is displayed as a document  
which can be referenced in the search result 306, the  
5 user can identify the referenced document by selecting  
this and pressing OK.

Fig. 4 is a diagram showing an example 400 of  
a screen for converting a reference document to that  
conforming to a country to which an application is to  
10 be made. Here, the user has selected an application to  
the country B with a selection button 401, and  
specified an application with a selection button 402.  
This example relates to a commercially available drug.  
The user also selects a capsule as the shape of the  
15 drug with a selection button 403, and selects "not  
adjusted" for components with a selection button 404.  
Instructions are made to prompt the user to select a  
plurality of application methods, other than the  
country name, as mentioned above, because application  
20 documents may differ in the type, number, contents and  
the like in accordance with detailed application  
conditions such as the use, shape of drug, change in  
components, and the like, depending on the type of  
industry associated with the application. As the user  
25 has specified required conditions, the presence or  
absence of reusable data, and information 405 on  
required application documents are displayed from the  
previously identified referenced documents.

Fig. 5 is a flow chart for explaining the processing operation for converting an application document to that conforming to a country to which an application is made. In the following, the processing operation will be explained.

(1) First, the reference document specifying unit 209 prompts the user to specify a document 306 to be referenced. Manipulations for specifying the document are performed as previously described in connection with Fig. 3 (step 501).

(2) Next, the application document specifying unit 210 prompts the user to specify a country 401 to which the application is made, and conditions such as the use 402, shape of drug 403, components 404 and the like, as methods which can be specified in that country. The manipulations for specifying are performed as previously described in connection with Fig. 4 (step 502).

(3) The pertinent document data detection unit 211 acquires data on the reference document 306 for a document specified by the previously described manipulations and resulting processing, references each data in the world-wide standard information internal data creation/storage unit 202, country-A published information internal data creation/storage unit 204, country-B published information internal data creation/storage unit 206, and country-A internal data/country-B internal data cross reference unit 207,



detects data which satisfies the conditions on the use  
402, shape of drug 403, and components 404 that are to  
be applied in the country 401 to which the application  
is made, as described in connection with Fig. 4, and  
5 provides the user with reusable data (step 503).

In the exemplary screen 400 described in  
connection with Fig. 4, the result presented at the  
foregoing step 503 states that application 1 -  
application 9 are required for the application, and  
10 reusable reference data exist for application 1,  
application 5, application 7, application 8 and  
application 9. Here, the user selects whether an  
automatic conversion is performed for required  
documents (407) or the user manually edits them (408),  
15 followed by a transition to the next procedure. Here,  
the description continues on the assumption that the  
automatic conversion 407 is selected. For manually  
editing the required documents, an existing document  
editing function may be used.

20 Fig. 6 is a diagram showing an exemplary  
automatic conversion screen 601 for conversion to an  
application conforming to the country B when the  
automatic conversion is specified. For automatically  
converting the application 1, an automatic translation  
25 program is started at 602 to translate from a language  
in the country A to a language in the country B. Also,  
a format conversion processing program is started at  
603 to automatically convert a format for the country A

to a format for the country B. After the conversion has been made, a selection is made as to whether the converted contents are stored as they are (604) or further manually edited (605), followed by termination of the processing. Similar processing is repeated for each application, and the processing proceeds to an application processing confirmation screen at the time all of document 1 - document 9 required for the application to the country B have been prepared.

Fig. 7 is a diagram showing an example 701 of the application processing confirmation screen which is displayed at the time all of the document 1 - document 9 required for the application to the country B have been prepared. As displayed on the example 701 of the application processing confirmation screen, assume that all of application 1 - application 9 have been prepared. Here, the user selects whether processing for confirming the examination contents is executed or processing for preserving the examination contents and confirming them at a later time with a confirmation button 702 or a preservation button 703. Assume herein that the user selects the confirmation button 702. This selection causes the examination content confirmation unit 215 to confirm whether or not each application document includes any description which violates the examination criteria in the country B.

Fig. 8 is a flow chart for explaining the processing operation performed by the examination

content confirmation unit to confirm whether or not any description violates the examination criteria in the country B. In the following, this processing operation will be explained along the flow chart.

5                   (1) One of the application documents is read, and the document data is compared with each data in the world-wide standard information internal data creation/storage unit 202, country-A published information internal data creation/storage unit 204,  
10 country-B published information internal data creation/storage unit 206, and country-A internal data/country-B internal data cross reference unit 207 to confirm whether or not there are descriptions which violate the examination criteria (step 801).

15                   (2) If a violation is found in the processing at step 801, the contents of the violation are outputted as a message. Assume herein, for example, that a violation is found in a description in application 1. Then in the shown example, outputted as  
20 a message 704 are the contents indicating that a permission could be accepted in the country A even if 1 % of a component called "pharmaceutical component  $\alpha$ " is included, whereas any commercially available drug cannot be accepted according to the examination  
25 criteria in the country B unless the component called "pharmaceutical component  $\alpha$ " is equal to or less than 0.5 % (step 802).

(3) After completing the foregoing

processing for one application, a check is made as to whether or not more documents (applications) remain, and the processing returns to step 801 to continue the processing for confirming the contents of the next  
5 document, if any. If no document remains, the processing is terminated (step 803).

The message 704 outputted in the processing at step 802 is displayed as shown in the exemplary display screen shown in Fig. 7. When a message is  
10 outputted to indicate that an improper expression is included in application 1, the user performs processing for changing the described contents in application 1 to match data (705).

Fig. 9 is a diagram showing an example of a  
15 data matching screen for changing described contents of an application. In the example shown in Fig. 9, since it has been found that application 1 includes an improper description, data 902 on application 1 is displayed in the displayed screen. Then, the data on  
20 the application 1 is displayed with the improper portion of the description underlined. When component data of concern is changed in accordance with the document data correlation rule defining unit 217, a group of data associated therewith must be changed as  
25 well. An example of outputting this as a message is displayed as shown at 903.

Fig. 10 is a flow chart for explaining the processing operation in the document data matching

unit. In the following, this processing operation will be explained along the flow chart.

(1) Since application 1 includes a description which violates the examination criteria,  
5 correlated data is detected for data which is requested for a change with reference to the document data correlation rule defining unit 217 (step 1001).

(2) A list of a group of replaceable reference data is presented to the user in regard to  
10 data identified as correlated. Such a group of reference data can be acquired from the A-country application document information 104. In the example shown in this figure, 1 %, 0.8 %, 0.5 %, 0.08 mg of the pharmaceutical component  $\alpha$ , and the like are  
15 illustrated as a group of reusable reference data (step 1002).

(3) The user selects data from the list presented in the foregoing manner, and replaces with this data to update the document data (step 1003).

20 Turning back to the exemplary display screen shown in Fig. 9, this example shows that when component data is changed, clinical data associated therewith must be changed. Accordingly, as the user changes the associated data, a group of replaceable associated data  
25 is displayed as 904. This exemplary screen shows, for example, that clinical data exist respectively when 1 %, 0.8 %, 0.5 %, 0.1 % and 0.08 mg of pharmaceutical component  $\alpha$  are used, as clinical data which are

associated data, and the user selects desired data for replacement. Since the criteria in the country B determines that a commercially available drug shall include 0.5 % or less of pharmaceutical component  $\alpha$ ,

5 the user selects 0.5 % of pharmaceutical component  $\alpha$ , and also replaces the clinical data with such data that is derived when 0.5 % of pharmaceutical component  $\alpha$  is used, with a replacement button 905. This replacement results in replacement of all associated data to ensure  
10 the matching of data within the application. Finally, the user selects whether or not application 1 after the replacement is preserved or not with a button 906. After terminating the confirmation for all the applications, the processing proceeds to manipulations  
15 for submitting the applications.

Fig. 11 is a diagram showing an example 1101 of an application submission screen. The exemplary screen shown in Fig. 11 is displayed after confirming that the confirmation has been terminated for the  
20 examination contents for all the application documents, and the user selects whether or not the applications are immediately submitted in this state, or the applications are canceled and preserved for an application at a later time. Here, description  
25 continues on the assumption that the user selects to submit the applications. The application processing unit 218 outputs the processing result as a message 1102, shown in the figure, when an electronic

application is processed to submit the applications.  
In the example of this figure, the processing result  
records an application request hour within the country  
B, and a request time converted into the international  
5 standard time, and information on the submitted  
documents and submission time (all information utilized  
for the application, such as an updated date and the  
like of reference information) is preserved. The  
application documents are stored as a document file, in  
10 which case the document file is assigned XXXIILLLLKKKK  
as a document ID. The product name in the country B is  
"gastrointestinal drug  $\alpha$ ." Here, information inherent  
in the country B such as the product name can be freely  
determined by the user as a document attribute, by  
15 utilizing an existing document management system.

In the embodiment of the present invention  
described above, referring to information on  
application documents which have previously been  
applied and permitted, data included in the documents  
20 is reused to conveniently prepare an application to  
another country. The present invention is also capable  
of fetching information on standards, examination  
criteria and the like, individually determined in a  
plurality of country, together with the globally world-  
25 wide standard to assist in newly preparing an  
application which complies with such information.

In the foregoing embodiment of the present  
invention, a variety of processing executed in the

application preparation assisting system 106 can be implemented as a program executable by a processing unit within a computer system. Also, the processing program can be stored and provided in a portable  
5 recording medium such as a magnetic disk, an optical disk and the like.

As described above, according to the embodiment of the present invention, it is possible to fetch information on standards, examination criteria  
10 and the like, individually determined in a plurality of country, together with the globally world-wide standard, and to prepare an application which complies with such information. Also, according to the embodiment of the present invention, referring to  
15 information on application documents which have previously been applied and permitted, data included in the documents is reused to conveniently prepare an application to another country. Further, according to the embodiment of the present invention, since it is  
20 possible to store a log of a manipulation procedure created by the application preparation assisting system according to the embodiment of the present invention, information can be readily provided so that it can be viewed as audit data at a later time.

25 As described above, according to the present invention, the application preparation assisting system can assist in newly preparing an application which complies with information on the standard, examination

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criteria and the like determined in each country, or in  
reusing data included in application documents which  
have been previously applied or permitted in a certain  
country to conveniently prepare an application to  
5 another country.

Also, since the present invention stores the  
log of manipulation procedure for preparing an  
application, it is possible to readily provide  
information which can be viewed as audit data at a  
10 later time.

It should be further understood by those  
skilled in the art that the foregoing description has  
been made on embodiments of the invention and that  
various changes and modifications may be made in the  
15 invention without departing from the spirit of the  
invention and the scope of the appended claims.

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